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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/964,796 | 09/28/2001 | Maximilian Angel | 0050/51796 | 2868 |

20474 7590 06/07/2004

KEIL & WEINKAUF
1350 CONNECTICUT AVENUE, N.W.
WASHINGTON, DC 20036

EXAMINER

REDDICK, MARIE L.

ART UNIT

PAPER NUMBER

(71)

DATE MAILED 06/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

| | | |
|-----------------|--------------|--|
| Application No. | Applicant(s) | |
| 09/964,796 | ANGEL ET AL. | |
| Examiner | Art Unit | |
| Judy M. Reddick | 1713 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period for reply will be considered timely.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.65(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB08)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

Response to Amendment

1. The amendment filed on 03/15/04 has been entered, considered and is deemed sufficient to remove the rejection under 35 USC 112, first paragraph, as applied to claims 1-8, the Objection to claim 1 and the rejection under 35 USC 102(b)/103(a) over Armour(U.S. 3,433,701, as applied to claims 1-6 & 8) or Bergmeister et al(U.S. 3,817,896, as applied to claims 1-8) and the rejection under 35 USC 103(a) over Armour as applied to claim 7(see the Office Action of 12/19/03).

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-8 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Dragner et al(U.S. 5,354,803).

Dragner et al teach a surfactantless, formaldehyde-free polyvinyl alcohol graft copolymer binder emulsion for non-woven products comprising, on a solids basis, a) 12 to 35 % by weight of a fully hydrolyzed low or ultra low molecular weight polyvinyl alcohol(PVOH) and b) 65 to 88 % by weight of a vinyl and/or acrylic monomer(s) which is(are) graft copolymerized with the PVOH through emulsion polymerization. More

specifically, the copolymer binder emulsion is prepared by the free-radical emulsion copolymerization of vinyl and/or acrylic monomers in an aqueous system and in the presence of PVOH wherein the vinyl and acrylic monomers include alkyl (meth)acrylate monomers, vinyl acetate monomer, and hydroxyalkyl (meth)acrylate monomers and mixtures thereof and, optionally, ethylenically unsaturated mono- and dicarboxylic acids such as (meth)acrylic acid, maleic acid and multifunctional monomers such as divinyl benzene(the Abstract, col. 2, lines 1-68, col. 3, lines 4-29,col. 4, lines 8-19 and the Claims, especially claims 1, 6 & 10). Dragner et al therefore anticipate the instantly claimed invention with the understanding that the copolymer and process for preparing said copolymer per Dragner et al overlaps in scope with the claimed water-soluble or water-dispersible copolymer and process of preparation of said water-soluble or dispersible copolymer obtained by free-radical polymerization of a monomer mixture and with the understanding that the copolymer genus is sufficiently small enough to engender anticipation of the claimed species(In re Schaumann, 572 F.2d 312, 197 USPQ 5 (CCPA 1978)).

As to the "consisting essentially of" clause, such limits the scope of a claim to the specified ingredients and to those that do not materially affect the basic and novel characteristics of a composition(E parte Davis, 80 USPQ 448 and In re Janakirama-Rao, 317 F 2d 951, 137 USPQ 893, CCPA 1963).

As to the limitation per claim 8, the use of the copolymer binder emulsion of Dragner et al in the coating of a pharmaceutical dosage form would be expected since the copolymer binder emulsion of Dragner et al is essentially the same as and made under essentially the same conditions as the claimed water-soluble or water-dispersible copolymer obtained by free-radical polymerization of a monomer mixture.

It has been held that where applicants claims a composition in terms of function, property of characteristic where said function is not explicitly shown by the reference and where the Examiner has explained why the function, property or characteristics is

considered inherent in the prior art, it is appropriate for the Examiner to make a rejection under both the applicable sections of 35 USC 102 and 35 USC 103 such that the burden is placed upon applicant to provide clear evidence that the respective compositions do, in fact, differ as provided for under the guise of *In re Best*, 195 USPQ 430, 433(CCPA 1977); *In re Fitzgerald et al*, 205 USPQ 594.

Even if it turns out that the Examiner has somehow missed the boat and the claims are not anticipated by the disclosure of Dragner et al, it would have been obvious to the skilled artisan to cull, from the disclosure of Dragner et al, the precisely defined copolymer and process of preparation thereof, as claimed, as per such having been within the general purview of the disclosure of Dragner et al and with a reasonable expectation of success.

Response to Arguments

5. Applicant's arguments with respect to claims 1-8 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

6. The prior art to Goldberg et al(U.S.3,203,918) is cited as of interest in teaching the preparation of vinyl alcohol-beta hydroxyalkyl acrylate copolymers. A rejection, in the future, may be made based on this prior art. However, since a viable rejection is outstanding on this record, as rejection, at this time, is not being made The prior art to Bolgiano et al is cited as of being illustrative of the general state of the art.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on

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the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Judy M. Reddick whose telephone number is (571)272-1110. The examiner can normally be reached on Monday-Friday, 6:30 a.m.-3:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Wu can be reached on (571)272-1114. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Judy M. Reddick
Judy M. Reddick
Primary Examiner
Art Unit 1713

JMR/jml
06.03.04